

DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health National Institute of Neurological Disorder and Stroke FOIA/PA Office, RKL 1, Suite 6054 6705 Rockledge Drive Bethesda, MD 20892

October 18, 2019

Karl Pensworth MuckRock News Dept MR 81751 411A Highland Ave Somerville, MA 02144

Re: FOIA Case Number: 52977

Dear Mr. Pensworth:

This acknowledges your Freedom of Information Act (FOIA) request addressed to National Institute of Neurological Disorder and Stroke (NINDS), National Institutes of Health (NIH), dated and received October 15, 2019. Your request was forwarded to this office because of our responsibilities under the FOIA for the National Institute of Neurological Disorder and Stroke (NINDS). You requested the following records related to grant R01NS099348:

- 1) The Statement of work/Scope on each sub-program or full contract with each contract-awardee or winning offeror company or institution, and the full Statement of work included with each contract; 2) Complete Documentation of Informed Consent from all human subjects utilized by or involved with this program in any way, including:
- 2. a) The FWA (Federal Wide Assurance) signed off by the Office of Human Research Protections, Department of Health and Human Services.
- 2. b) Detailed Informed consent documents including lists of consenting human subjects, specific information provided to human subjects, and signed documents from human subjects attesting to Informed Consent.
- 2. c) Any additional internal CIA document assuring compliance with the Common Rule signed off by the Institutional Review Board involved.
- 2. d) All affirmations of Compliance Oversight from the Office of Human Subject Research Protections.
- 2. e) All Waivers of Consent from the Secretary of Defense or any other federal agency, as applicable, including the full reasons for these waivers.
- 3) Complete documentation with precise details on Location and Field of Operation where scientific instruments and/or weapons are being utilized or tested, "wittingly" or "unwittingly," overtly or covertly, on human beings--namely US immigrants, citizens or any individuals present in the USA whether temporarily or permanently, currently or formerly.

We will send you all material consistent with the exemptions recognized by the FOIA. It is Department of Health and Human Services (HHS) policy to expunge certain types of information, including personal privacy information and confidential commercial information wherever they appear throughout the grant material. Examples of these types of information include: social security numbers, birth dates, percentage of effort, institutional base salary, source of private support, pending support, and any patentable material wherever they appear throughout the grant material. If you feel that this information should not be excluded from the material, please advise me and I will consult with the NIH Freedom of Information Officer.

We are asking the grantee to advise this office if release of the material you requested will adversely affect any patent rights or reveal other confidential commercial or financial information. Subsequent to receipt of such advice this office will make a decision regarding releasability. We will do everything possible to comply with your request in a timely manner. Please feel free to call me at 301-496-9737 for additional information or to inquire about the status of your request.

Provisions of the FOIA allow us to recover part of the cost of complying with your request. We shall charge you for records in accordance with the HHS FOIA regulations as they apply to "other" requesters. As an "other" category requester you will be charged for duplication at 10-cents per page although the first 100 pages are free; 2 hours of search time are free and thereafter search time is charged at the hourly rate (\$23.00, \$46.00, \$83.00) of the searcher; there is no charge for review time. Please be advised that the HHS FOIA Regulations allow us to charge for search time even if we do not locate any responsive records or if we determine that some or all of the responsive records are exempt under one of the FOIA's nine exemptions. If there are any fees associated with processing this request, you will be sent an invoice with our final response.

At any time during the processing of your request, you may contact the NINDS FOIA Public Liaison:

NINDS FOIA Public Liaison

Marianne Manheim
Rockledge I, Suite 6054
6705 Rockledge Drive
Bethesda, MD 20892
301-496-9737 (phone)
301-402-3604 (fax)
marianne.manheim@nih.gov (email)

Sincerely,

Luke Wymer

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Government Information Specialist, NINDS